AV-PHOS 250 NEUTRAL - sodium phosphate, dibasic, anhydrous, potassium phosphate, monobasic, and sodium phosphate, monobasic, monohydrate tablet
AvKARE, Inc.

Av-Phos 250 Neutral Tablets

Phosphorous Dietary Supplement - supplying 250 mg phosphorous per tablet

DESCRIPTION

Av-Phos 250 Neutral is a prescription phosphorous dietary supplement - supplying 250 mg phosphorous per tablet for use in the dietary management of hypophosphatemia and should be administered under the supervision of a licensed medical practitioner.

Supplement Facts **Serving Size: One Tablet**		
	Amount Per Serving	**% Daily Value**
Dibasic Sodium Phosphate Anhydrous	852 mg*	†
Monobasic Potassium Phosphate	155 mg*	†
Monobasic Sodium Phosphate Monohydrate	130 mg*	†

* Each tablet yields approximately 250 mg (25% DV for adults) of phosphorus, 298 mg sodium (13.0 mEq), and 45 mg of potassium (1.1 mEq).

† Daily Value not established

Other Ingredients: Microcrystalline Cellulose, Croscarmellose Sodium, Magnesium Stearate, Silicon Dioxide, Stearic Acid, HPMC 15cp, Polydextrose, PEG 4000 Titanium Dioxide.

ALLERGY STATEMENT

This product has been manufactured in a facility that also manufactures products containing tree nuts, peanuts, fish, egg, wheat, milk, soy and shellfish. Individuals with allergies to these substances should use discretion.

INDICATIONS AND USAGE

As a phosphorus supplement, each tablet supplies 25% of the U.S. Recommended Daily Allowance (U.S. RDA) of phosphorus for adults and children over 4 years of age.

Av-Phos 250 Neutral increases urinary phosphate and pyrophosphate.

CONTRAINDICATIONS

This product is contraindicated in patients with infected phosphate stones in the urinary tract, in patients with severely impaired renal function (less than 30% of normal) and in the presence of hyperphosphatemia.

PRECAUTIONS

General

This product contains potassium and sodium and should be used with caution if clinical management of these elements is desired. Some individuals may experience a mild laxative effect during the first few days of phosphate therapy; lower the daily dose until this effect subsides or, if necessary, discontinue the use of the product. Caution should be exercised when prescribing this product in the following conditions: Cardiac disease (particularly in patients receiving digitalis); severe adrenal insufficiency (Addison's disease); acute dehydration; severe renal insufficiency; renal function impairment or chronic renal disease; extensive tissue breakdown (such as with severe burns); myotonia congenita; cardiac failure; cirrhosis of the liver or severe hepatic disease; peripheral or pulmonary edema; hypernatremia; hypertension; toxemia of pregnancy; hypoparathyroidism; and acute pancreatitis. High serum phosphate levels may increase the incidence of extraskeletal calcification.

Information for Patients

Patients with kidney stones may pass old stones when phosphate therapy is started and should be warned of this possibility. Patients should be advised to avoid the use of antacids containing aluminum, magnesium, or calcium because they may prevent the absorption of phosphate.

Laboratory Tests

Careful monitoring of renal function and serum calcium, phosphorus, potassium, and sodium may be required at periodic intervals during phosphate therapy. Other tests may be warranted in some patients, depending on conditions.

Drug Interactions

The use of antacids containing magnesium, aluminum, or calcium in conjunction with phosphate preparations may bind the phosphate and prevent its absorption. Concurrent use of antihypertensive drugs or corticosteroids with sodium phosphate may result in hypernatremia. Calcium-containing preparations and/or Vitamin D may antagonize the effects of phosphates in the treatment of hypercalcemia. Potassium-containing medication or potassium-sparing diuretics may cause hyperkalemia. Patients should have serum potassium level determinations at periodic intervals.

Carcinogenesis, Mutagenesis, Impairment of Fertility

No long term or reproduction studies in animals or humans have been performed with Av-Phos 250 Neutral to evaluate its carcinogenic, mutagenic, or impairment of fertility potential.

Pregnancy and Lactation

Animal reproduction studies have not been conducted with Av-Phos 250 Neutral. It is also not known whether this product can cause fetal harm when administered to a pregnant woman or can affect reproductive capacity. This product should be given to a pregnant woman only if clearly needed.

It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when this product is administered to a nursing woman.

Pediatric Use

See DIRECTIONS FOR USE.

SIDE EFFECTS

Gastrointestinal upset (diarrhea, nausea, stomach pain, or vomiting) may occur with phosphate therapy. Bone and joint pain and possibly osteomalacia could occur.

Adverse effects due to sodium or potassium may be observed: headache; dizziness; mental confusion; seizures; weakness or heaviness of legs; unusual tiredness or weakness; numbness, tingling, pain or weakness of hands or feet; numbness or tingling around lips; fast or irregular heartbeat; shortness of breath or troubled breathing; swelling of feet or lower legs; unusual weight gain; low urine output;

unusual thirst.

DIRECTIONS FOR USE

Av-Phos 250 Neutral tablets should be taken with a full glass of water, with meals and at bedtime.

Adults

One or two tablets, four times daily;

Pediatric patients over 4 years of age

One tablet four times daily.

Pediatric Patients under 4 years of age

Use only as directed by licensed healthcare practitioner.

STORAGE

Store at 20° to 25°C (68° to 77°F). Excursions permitted to 15° to 30°C (59° to 86°F). Protect from light and moisture. Dispense in a tight, light-resistant container. Notice: Contact with moisture may produce surface discoloration or erosion.

HOW SUPPLIED

Av-Phos 250 Neutral is supplied as white tablet, imprinted "V268" dispensed in bottles of 100 tablets.

NDC 42291-152-01

This product may - under certain circumstances, be dispensed through a certified mail-order program so long as there is record of prescription AND confirmation that the patient is under licensed medical supervision.

KEEP THIS OUT OF REACH OF CHILDREN

All prescriptions using this product shall be pursuant to state statutes as applicable. This is not an Orange Book product.

Call your licensed medical practitioner about side effects. You may report side effects by calling AvKARE, Inc. at 1-855-361-3993 or FDA at 1-800-FDA-1088.

Manufactured for:
AvKARE, Inc.
Pulaski, TN 38478

Mfg. Rev. 05/15

AV Rev. 04/16 (P)

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

AvKARE

NDC 42291-152-01

Av-Phos 250 Neutral

Prescription Phosphorous Dietary Supplement - Supplying 250 mg per tablet

100 TabletsMust be used under the supervision of a physician.

Supplement Facts

Serving Size: One Tablet		
	Amount Per Serving	**% Daily Value**
Dibasic Sodium Phosphate Anhydrous	852 mg*	†
Monobasic Potassium Phosphate	155 mg*	†
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Other Ingredients: Microcrystalline Cellulose, Croscarmellose Sodium, Magnesium Stearate, Silicon Dioxide, Stearic Acid, HPMC 15cp, Polydextrose, PEG 4000, Titanium Dioxide.

Allergy: Product may be exposed to tree nuts, peanuts, fish, egg, wheat, milk, soy and shellfish during manufacture. See Prescribing Information.

DESCRIPTION: Av-Phos 250 Neutral is a prescription phosphorous dietary supplement - supplying 250 mg per tablet for use in the dietary management of hypophosphatemia and should be administered under the supervision of a licensed medical practitioner.

DIRECTIONS FOR USE: Av-Phos 250 Neutral should be taken with a full glass of water, with meals and at bedtime. Adults: One or two tablets four times daily; Pediatric Patients over 4 years of age: One tablet four times daily; Pediatric Patients under 4 years of age: Use only as directed by a licensed healthcare practitioner.

PRECAUTIONS, CONTRAINDICATIONS, SIDE EFFECTS: See Prescribing Information.

KEEP OUT OF REACH OF CHILDREN.

STORAGE: Store at 20° to 25°C (68° to 77°F). Excursions permitted to 15° to 30°C (59° to 86°F). Protect from light and moisture. Dispense in a tight, light-resistant container. Notice: Contact with moisture may produce surface discoloration or erosion.

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AV-PHOS 250 NEUTRAL

sodium phosphate, dibasic, anhydrous, potassium phosphate, monobasic, and sodium phosphate, monobasic, monohydrate tablet

Product Information			
Product Type	DIETARY SUPPLEMENT	**Item Code (Source)**	NHRIC:42291-152(NDC:69543-268)
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
Sodium Phosphate, Dibasic, Anhydrous (UNII: 22ADO53M6F) (Phosphate Ion - UNII:NK08V8K8HR, Sodium Cation - UNII:LYR4M0NH37)	Sodium Phosphate, Dibasic, Anhydrous	852 mg
Potassium Phosphate, Monobasic (UNII: 4J9FJ0HL51) (Phosphate Ion - UNII:NK08V8K8HR, Potassium Cation - UNII:295O53K152)	Potassium Phosphate, Monobasic	155 mg
Sodium Phosphate, Monobasic, Monohydrate (UNII: 593YOG76RN) (Phosphate Ion - UNII:NK08V8K8HR, Sodium Cation - UNII:LYR4M0NH37)	Sodium Phosphate, Monobasic, Monohydrate	130 mg

Inactive Ingredients	
Ingredient Name	**Strength**
Cellulose, Microcrystalline (UNII: OP1R32D61U)	
Croscarmellose Sodium (UNII: M28OL1HH48)	
Magnesium Stearate (UNII: 70097M6I30)	
Silicon Dioxide (UNII: ETJ7Z6XBU4)	
Stearic Acid (UNII: 4ELV7Z65AP)	
Polydextrose (UNII: VH2XOU12IE)	
Polyethylene Glycol 4000 (UNII: 4R4HFI6D95)	
Titanium Dioxide (UNII: 15FIX9V2JP)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NHRIC:42291-152-01	100 in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
DIETARY SUPPLEMENT		12/08/2015	

Supplement Facts

Serving Size : **Serving per Container :**

	Amount Per Serving	% Daily Value
color		
scoring	1	
shape		
size (solid drugs)	19 mm	
imprint		

Labeler - AvKARE, Inc. (796560394)

Revised: 4/2016 AvKARE, Inc.